

**FILED**

2008 JUN 23 P 12:16

U.S. DISTRICT COURT  
BRIDGEPORT, CONN

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF CONNECTICUT

UNITED STATES OF AMERICA,

Plaintiff,

v.

PFIZER, INC.,

Defendant.

Civil Action No.

**CONSENT DECREE**

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Plaintiff United States of America, on behalf of the United States Environmental Protection Agency ("EPA"), has filed a Complaint in this action under Section 113(b) of the Clean Air Act ("Act"), 42 U.S.C. § 7413(b), concurrently with this Consent Decree. The Complaint alleges that Defendant, Pfizer, Inc. ("Defendant" or "Pfizer"), violated Section 112 of the Act, 42 U.S.C. § 7412, and regulations promulgated thereunder, set forth at 40 C.F.R. Part 63, Subpart H and Subpart GGG, pertaining to leak detection and repair ("LDAR") requirements for pharmaceutical manufacturing facilities.

The Complaint against Defendant alleges that Pfizer, during the operation of its former pharmaceutical manufacturing facility at 445 Eastern Point Road in Groton, Connecticut ("Facility"), failed to comply with the following LDAR requirements: Repairing and Re-testing of Leaking Equipment; Sealing of Open-ended Lines; Applying Proper Gas/Liquid Pressure Test Methods and Procedures to Detect Leaks; and Keeping Adequate Records of Pressure Tests and Pressure Test Results.

On August 17, 2006, EPA issued an Administrative Order to Pfizer under Section 113(a) of the Act, 42 U.S.C. § 7413(a), in which EPA cited Pfizer for failure to properly implement an LDAR program at the Facility, as required by Subpart H and Subpart GGG, citing the same requirements referenced in the Complaint. Subsequent to the date of the Administrative Order, Pfizer has implemented appropriate corrective measures as identified and certified to in this Decree.

Defendant does not admit any liability to the United States arising out of the transactions or occurrences alleged in the Complaint.

The Parties recognize, and the Court by entering this Consent Decree finds, that this Consent Decree has been negotiated by the Parties in good faith and will avoid litigation between the Parties and that this Consent Decree is fair, reasonable, and in the public interest.

NOW, THEREFORE, before the taking of any testimony, without the adjudication or admission of any issue of fact or law except as provided in Section I, and with the consent of the Parties, IT IS HEREBY ADJUDGED, ORDERED, AND DECREED as follows:

### I. JURISDICTION AND VENUE

1. This Court has jurisdiction over the subject matter of this action, pursuant to 28 U.S.C. §§ 1331, 1345, and 1355, and Section 113(b) of the Act, 42 U.S.C. § 7413(b), and over the Parties. Venue lies in this judicial district pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 28 U.S.C. §§ 1391(b) and (c), and 1395(a), because the violations alleged in the Complaint are alleged to have occurred in, and Defendant conducts business in, this judicial district. For purposes of this Decree, or any action to enforce this Decree, Defendant consents to the Court's jurisdiction over this Decree and any such action and over Defendant and consents to venue in this judicial district.

2. For purposes of this Consent Decree, Defendant agrees that the Complaint states claims upon which relief may be granted pursuant to Sections 112 and 113 of the Act, 42 U.S.C. §§ 7412 and 7413.

### II. APPLICABILITY

3. The obligations of this Consent Decree apply to and are binding upon the United States, and upon Defendant and any successors, assigns, or other entities or persons otherwise bound by law.

4. No transfer of ownership or operation of the Facility shall relieve Defendant of its obligation to ensure that the terms of the Decree are implemented.

5. Defendant shall provide a copy of this Consent Decree to all officers, employees, and agents whose duties might reasonably include compliance with any provision of this Decree.

6. In any action to enforce this Consent Decree, Defendant shall not raise as a defense the failure by any of its officers, directors, employees, or agents to take any actions necessary to comply with the provisions of this Consent Decree.

### III. DEFINITIONS

7. Terms used in this Consent decree that are defined in the Act or in regulations promulgated pursuant to the Act shall have the meanings assigned to them in the Act or such regulations, unless otherwise provided in this Decree. Whenever the terms set forth below are used in this Consent Decree, the following definitions shall apply:

a. "Complaint" shall mean the complaint filed by the United States in this civil action;

b. "Consent Decree" or "Decree" shall mean this Decree and all appendices attached hereto listed in Section XVI;

c. "Day" shall mean a calendar day unless expressly stated to be a business day. In computing any period of time under this Consent Decree, where the last day would fall on a Saturday, Sunday, or federal holiday, the period shall run until the close of business of the next business day;

d. "Defendant" shall mean Pfizer, Inc.;

c. "EPA" shall mean the United States Environmental Protection Agency and any of its successor departments or agencies;

f. "Effective Date" shall have the definition provided in Section X.

g. "Facility" shall mean Defendant's former pharmaceutical manufacturing facility, located at 445 Eastern Point Road in Groton, Connecticut.

h. "Paragraph" shall mean a portion of this Decree identified by an arabic numeral;

i. "Parties" shall mean the United States and Defendant;

j. "Section" shall mean a portion of this Decree identified by a roman numeral; and

k. "United States" shall mean the United States of America, acting on behalf of EPA.

#### IV. CIVIL PENALTY

8. Within 30 Days after the Effective Date of this Consent Decree, Defendant shall pay the sum of \$975,000 as a civil penalty.

9. Defendant shall pay the civil penalty due by FedWire Electronic Funds Transfer ("EFT") to the U.S. Department of Justice in accordance with written instructions to be provided to Defendant, by the Financial Litigation Unit of the U.S. Attorney's Office for the District of Connecticut. At the time of payment, Defendant shall send a copy of the EFT authorization form and the EFT transaction record, together with a transmittal letter, which shall state that the payment is for the civil penalty owed pursuant to the Consent Decree in *United States v. Pfizer, Inc.*, and shall reference the civil action number and DOJ case number 90-5-2-1-09183, to the

United States in accordance with Section IX of this Decree (Notices); by email to acctsreceivable.CINWD@epa.gov; and by mail to:

EPA Cincinnati Finance Office  
26 Martin Luther King Drive  
Cincinnati, Ohio 45268

10. Defendant shall not deduct any penalties paid under this Decree pursuant to this Section or Section VI (Stipulated Penalties) in calculating its federal income tax.

#### V. COMPLIANCE REQUIREMENTS

11. By signing this Consent Decree, Defendant certifies, under penalty of law, that the corrective compliance measures, identified in Appendix A, have been implemented at the Facility to address alleged violations of LDAR work practice, testing and recordkeeping requirements, set forth in 40 C.F.R. Part 63, Subpart H and Subpart GGG.

12. By signing this Consent Decree, Defendant further certifies, under penalty of law, that: (i) pharmaceutical manufacturing operations at the Facility ceased on or before January 8, 2008; and that (ii) Defendant has no foreseeable plans to resume pharmaceutical manufacturing operations at the Facility that would be subject to LDAR requirements, promulgated pursuant to Section 112 of the Act, 42 U.S.C. § 7412.

13. If Defendant resumes pharmaceutical manufacturing operations at the Facility at anytime within three years of the Effective Date of this Decree, Defendant shall notify the United States in accordance with Section IX of this Decree at least 30 days in advance of such event.

## **VI. STIPULATED PENALTIES**

14. If Defendant fails to pay the civil penalty required to be paid under Section IV of this Decree (Civil Penalty) when due, Defendant shall pay a stipulated penalty of \$1000 per Day for each Day that the payment is late.

15. Stipulated penalties under this Section shall begin to accrue on the Day after performance is due or on the Day a violation occurs, whichever is applicable, and shall continue to accrue until performance is satisfactorily completed or until the violation ceases.

16. Defendant shall pay any stipulated penalty within 30 Days of receiving the United States' written demand.

17. The United States may, in the unreviewable exercise of its discretion, reduce or waive stipulated penalties otherwise due under this Consent Decree.

18. Defendant shall pay stipulated penalties owing to the United States in the manner set forth and with the confirmation notices required by Paragraph 9, except that the transmittal letter shall state that the payment is for stipulated penalties and shall state for which violation(s) the penalties are being paid.

19. If Defendant fails to pay stipulated penalties according to the terms of this Consent Decree, Defendant shall be liable for interest on such penalties, as provided for in 28 U.S.C. § 1961, accruing as of the date payment became due. Nothing in this Paragraph shall be construed to limit the United States from seeking any remedy otherwise provided by law for Defendant's failure to pay any stipulated penalties.



20. Subject to the provisions of Section VII of this Consent Decree (Effect of Settlement/Reservation of Rights), the stipulated penalties provided for in this Consent Decree shall be in addition to any other rights, remedies, or sanctions available to the United States for Defendant's violation of this Consent Decree or applicable law.

#### VII. EFFECT OF SETTLEMENT/RESERVATION OF RIGHTS

21. This Consent Decree resolves the civil claims of the United States for the violations alleged in the Complaint filed in this action through the date of the United States' Motion for Entry of this Decree or letter to the Court requesting entry of the Decree.

22. The United States reserves all legal and equitable remedies available to enforce the provisions of this Consent Decree, except as expressly stated in Paragraph 21. This Consent Decree shall not be construed to limit the rights of the United States to obtain penalties or injunctive relief under the Act or implementing regulations, or under other federal laws, regulations, or permit conditions, except as expressly specified in Paragraph 21.

23. This Consent Decree is not a permit, or a modification of any permit, under any federal, State, or local laws or regulations. Defendant is responsible for achieving and maintaining complete compliance with all applicable federal, State, and local laws, regulations, and permits; and Defendant's compliance with this Consent Decree shall be no defense to any action commenced pursuant to any such laws, regulations, or permits, except as set forth herein. The United States does not, by its consent to the entry of this Consent Decree, warrant or aver in any manner that Defendant's compliance with any aspect of this Consent Decree will result in compliance with provisions of the Clean Air Act, 42 U.S.C. § 7401 *et seq.*, or with any other provisions of federal, State, or local laws, regulations, or permits.

24. This Consent Decree does not limit or affect the rights of Defendant or of the United States against any third parties, not party to this Consent Decree, nor does it limit the rights of third parties, not party to this Consent Decree, against Defendant, except as otherwise provided by law.

25. This Consent Decree shall not be construed to create rights in, or grant any cause of action to, any third party not party to this Consent Decree.

#### VIII. COSTS

26. The Parties shall bear their own costs of this action, including attorneys' fees, except that the United States shall be entitled to collect the costs (including attorneys' fees) incurred in any action necessary to collect any portion of the civil penalty or any stipulated penalties due but not paid by Defendant.

#### IX. NOTICES

27. Unless otherwise specified herein, whenever notifications, submissions, or communications are required by this Consent Decree, they shall be made in writing and addressed as follows:

To the United States:

Chief, Environmental Enforcement Section  
Environment and Natural Resources Division  
U.S. Department of Justice  
Box 7611 Ben Franklin Station  
Washington, D.C. 20044-7611  
Re: DOJ No. 90-5-2-1-09183

and

Hugh W. Martinez, Senior Enforcement Counsel  
U.S. Environmental Protection Agency

Region 1  
1 Congress Street  
Suite 1100 (Mail Code: SEL)  
Boston, MA 02114-2023

To EPA:

Hugh W. Martinez, Senior Enforcement Counsel  
U.S. Environmental Protection Agency  
Region 1  
1 Congress Street  
Suite 1100 (Mail Code: SEL)  
Boston, MA 02114-2023

To Defendant:

Michael G. Mahoney, Esq.  
Assistant General Counsel, EHS - Legal  
Pfizer, Inc.  
235 E. 42<sup>nd</sup> Street  
New York, NY 10017-5755

and

Brian C. Freeman, Esq.  
Robinson & Cole LLP  
280 Trumbull Street  
Hartford, CT 06103-3597

28. Any Party may, by written notice to the other Parties, change its designated notice recipient or notice address provided above.

29. Notices submitted pursuant to this Section shall be deemed submitted upon mailing, unless otherwise provided in this Consent Decree or by mutual agreement of the Parties in writing.

#### **X. EFFECTIVE DATE**

30. The Effective Date of this Consent Decree shall be the date upon which this Consent Decree is entered by the Court or a motion to enter the Consent Decree is granted, whichever occurs first, as recorded on the Court's docket.

#### **XI. RETENTION OF JURISDICTION**

31. The Court shall retain jurisdiction over this case until termination of this Consent Decree for the purpose of interpreting and enforcing the terms of this Decree.

#### **XII. TERMINATION**

32. After Defendant has paid the full civil penalty as required by Paragraph 8, and any accrued stipulated penalties and any interest on such stipulated penalties as required by this Consent Decree, Defendant may serve upon the United States a Request for Termination, stating that Defendant has satisfied those requirements, together with all necessary supporting documentation, and requesting that the United States certify in writing that all of Defendant's obligations under this Consent Decree have been satisfactorily completed.

33. If the United States certifies that all of Defendant's obligations under this Consent Decree have been satisfactorily completed, then either Party may move to terminate this Consent Decree based on the representations that Defendant has met all of its requirements under this Consent Decree, by attaching the United States' certification. If the United States does not respond to Defendant's Request for Termination, within 60 Days of the date of such Request, then Defendant may move to terminate this Consent Decree based on the representations that it has met all of its requirements under this Consent Decree, by attaching its own certification to this effect.

### XIII. SIGNATORIES/SERVICE

34. Each undersigned representative of Defendant and the Assistant Attorney General for the Environment and Natural Resources Division of the Department of Justice certifies that he or she is fully authorized to enter into the terms and conditions of this Consent Decree and to execute and legally bind the Party he or she represents to this document.

35. This Consent Decree may be signed in counterparts, and its validity shall not be challenged on that basis. Defendant agrees to accept service of process by mail with respect to all matters arising under or relating to this Consent Decree and to waive the formal service requirements set forth in Rules 4 and 5 of the Federal Rules of Civil Procedure and any applicable Local Rules of this Court including, but not limited to, service of a summons and complaint.

### XIV. INTEGRATION

36. This Consent Decree and its appendix constitutes the final, complete, and exclusive agreement and understanding among the Parties with respect to the settlement embodied in the Decree and supercedes all prior agreements and understandings, whether oral or written, concerning the settlement embodied herein. No other document, nor any representation, inducement, agreement, understanding, or promise, constitutes any part of this Decree or the settlement it represents, nor shall it be used in construing the terms of this Decree.

### XV. FINAL JUDGMENT

37. Upon approval and entry of this Consent Decree by the Court, this Consent Decree shall constitute a final judgment of the Court as to the United States and Defendant.

**XVI. APPENDIX**

38. The following appendix is attached to and part of this Consent Decree:

"Appendix A" is the List of Corrective Compliance Measures Previously Implemented at the Facility.

Dated and entered this \_\_\_\_ day of \_\_\_\_\_, \_\_\_\_.

---

**UNITED STATES DISTRICT JUDGE**  
**District of Connecticut**

THE UNDERSIGNED PARTY enters into this Consent Decree in the matter of *United States v. Pfizer, Inc.*, (D. Conn.), relating to Pfizer's former pharmaceutical manufacturing facility in Groton, Connecticut.

**FOR THE UNITED STATES OF AMERICA:**

6-18-08

Date



RONALD J. TENPAS  
Assistant Attorney General  
Environment and Natural Resources Division  
United States Department of Justice  
P.O. Box 7611  
Washington, D.C. 20044-7611

6/19/08

Date

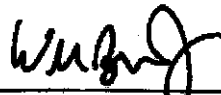


MARC BORODIN  
Trial Attorney  
Environmental Enforcement Section  
Environment and Natural Resources Division  
U.S. Department of Justice  
P.O. Box 7611  
Washington, D.C. 20044-7611

NORA DANNEHY  
Acting United States Attorney for the  
District of Connecticut

6/23/08

Date



WILLIAM M. BROWN, JR.  
Assistant U.S. Attorney  
District of Connecticut  
915 Lafayette Blvd, Room 309  
Bridgeport, CT 06604  
Phone: (203) 696-3022  
Facsimile: (203) 579-5575  
[william.m.brown@usdoj.gov](mailto:william.m.brown@usdoj.gov)

THE UNDERSIGNED PARTY enters into this Consent Decree in the matter of *United States v. Pfizer, Inc.*, (D. Conn.), relating to Pfizer's former pharmaceutical manufacturing facility in Groton, Connecticut.

04/30/08  
Date

Susan Studlien  
SUSAN STUDLIEN  
Director  
Office of Environmental Stewardship  
U.S. Environmental Protection Agency, Region 1  
1 Congress Street, Suite 1100  
Boston, MA 02114-2023

4-24-08  
Date

Hugh W. Martinez  
HUGH W. MARTINEZ  
Senior Enforcement Counsel  
Office of Environmental Stewardship  
U.S. Environmental Protection Agency, Region 1  
1 Congress Street, Suite 1100 (Mail Code: SEL)  
Boston, MA 02114-2023



THE UNDERSIGNED PARTY enters into this Consent Decree in the matter of *United States v. Pfizer, Inc.*, (D. Conn.), relating to Pfizer's former pharmaceutical manufacturing facility in Groton, Connecticut.

June 18, 2008

Date

  
GRANTA Y. NAKAYAMA

Assistant Administrator

Office of Enforcement and Compliance Assurance

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, D.C. 20460

June 11, 2008

Date

  
ADAM M. KUSHNER

Director, Air Enforcement Division

Office of Enforcement and Compliance Assurance

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, D.C. 20460

**FOR DEFENDANT PFIZER, INCORPORATED:**

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## **APPENDIX A**

### **List of Corrective Compliance Measures Previously Implemented at the Facility**

By signing this Consent Decree, Defendant certifies, under penalty of law, that the corrective compliance measures listed below were implemented at the Facility to address alleged violations of LDAR requirements in 40 C.F.R. Part 63, Subpart H and Subpart GGG, prior to the lodging of this Consent Decree. Defendant does not admit that such measures are necessarily required under 40 C.F.R. Part 63, Subpart H and Subpart GGG.

1. Between September 22, 2006 and November 14, 2006, Pfizer officials provided 14 detailed LDAR refresher training sessions, lasting about 1 to 2 hours, to approximately 114 employees. Such LDAR training included the following areas of concern identified by EPA: (i) stabilization of test pressure before beginning testing and ensuring that test pressure is slightly above operating pressure; (ii) repetition of tests that exhibit a pressure rise; (iii) recommended work practices to ensure clear documentation of compliance in conformance with testing procedure requirements, including, applicable test time and recording of significant decimal digits for pressure drops; and (iv) post-test corrective actions if a test does not result in compliance;
2. Revision of the Facility LDAR procedures and pressure test forms to clearly demonstrate compliance under the regulations;
3. Appointment of a Facility-wide LDAR Coordinator to oversee proper LDAR testing and recordkeeping;
4. Retention of independent third-party consultant to conduct review of the Facility's LDAR test results for compliance assurance; and
5. Facility shut-down and re-testing in late October through early November 2006, to ensure compliance.